Dated: September 5, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10236 and CMS–10079]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Disclosure of Financial Relationships Report (''DFRR''); *Form Number:* CMS–10236 (OMB#: 0938–New); *Use:* Section 1877(f) of the Social Security Act requires that each entity providing covered items or services for which payment may be made shall provide the Secretary with information concerning the entity's ownership, investment, and compensation arrangements, in such form, manner, and at such times as the Secretary shall specify. DFRR is a new collection instrument that will be used by CMS to obtain information necessary to analyze each hospital's compliance with section 1877 of the Social Security Act (''the physician self-referral law''), and implementing regulations (42 Code of Federal Regulations, Subpart J). Based upon public comments and CMS review, a number of changes were made to the DFRR. The most significant change to the DFRR involves the addition of worksheets to capture information concerning indirect ownership. Refer to the ''Summary of Changes to the Disclosure of Financial Relationships Report (DFRR)'' document to view a list of changes. *Frequency:* Reporting—Once; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 3,000.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Hospital Wage Index Occupational Mix Survey and Supporting Regulations in 42 CFR, section 412.64; *Use:* Section 304(c) of Public Law 106–554 mandates an occupational mix adjustment to the wage index, requiring the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. The 2007/2008 revised survey will provide for the collection of hospital-specific wages and hours data for a 1-year prospective reporting period (July 1, 2007 through June 30, 2008), additional clarifications to the survey instructions, the elimination of the RN subcategories, some refinements to the definitions for the occupational categories, and the inclusion of additional cost centers that typically provide nursing services. Additional revisions include expanding the current cost center list to include cost center 57—Renal Dialysis. For more details, please refer to the ''Medicare Wage Index Occupational Mix Survey—Summary of Changes'' document.

The 2007/2008 Medicare occupational mix survey will be applied beginning with the FY 2010 wage index. Each of the approximately 3,600 inpatient prospective payment system providers participating in the Medicare program will be required to complete the revised Medicare Wage Index Occupational Mix Survey. The revised survey will be forwarded to hospitals through CMS's fiscal intermediaries and will be made available on CMS's Web site. *Form Number:* CMS–10079 (OMB#: 0938–0907); *Frequency:* Reporting: Yearly, biennially and occasionally; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 3,600; *Total Annual Responses:* 3,600; *Total Annual Hours:* 1,728,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: September 6, 2007.

Michelle Shortt,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0336]

Guidance for Industry and Food and Drug Administration Staff; Commercially Distributed Analyte Specific Reagents: Frequently Asked Questions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions.'' FDA is issuing this guidance to clarify the regulations regarding commercially distributed ASRs and the role and responsibilities of ASR manufacturers. The draft of this guidance was issued September 7, 2006.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

Manufacturers should ensure their Class II or Class III in vitro diagnostic devices, that are currently inappropriately labeled and marketed as ASRs, comply with the law by September 15, 2008.

ADDRESSES: Submit written requests for single copies of the guidance document